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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|------------------------|---------------------|------------------|
| 10/572,970 | 11/21/2006 | Jonathan Edward Creeth | CB60508 | 4572 |
| 20462 7590 06/17/2011 GlaxoSmithKline GLOBAL PATENTS -US, UW2220 P. O. BOX 1539 KING OF PRUSSIA, PA 19406-0939 | | | | |
| EXAMINER MAEWALL, SNIGDEHA | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1612 | | | | |
| NOTIFICATION DATE | | DELIVERY MODE | | |
| 06/17/2011 | | ELECTRONIC | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| | | |
|------------------------------|------------------------|-------------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/572,970 | CREETH, JONATHAN EDWARD |
| | Examiner | Art Unit |
| | SNIGDHA MAEWALL | 1612 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21 and 22 is/are pending in the application.
- 4a) Of the above claim(s) 1-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Summary

1. Receipt of applicant's arguments, amended claim and **RCE** filed on 04/14/11 is acknowledged.

Claims **1-20** have been cancelled.

New claims **21-22** are under prosecution.

(All references are of record)

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims **21-22** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21-22 recites the limitations in parenthesis which makes the claim indefinite because it is not clear whether the limitations are really the limitations or not.

Instant claim has been amended to recite the term "consisting of a soluble calcium sequestering agent that is not an oxidizing agent and an orally acceptable vehicle and abrasive in a proportion of 0 to 5 wt%. The transitional phrase

"consisting of" excludes any element, step, or ingredient not specified in the claim. In re Gray, 53 F.2d 520, 11 USPQ 255 (CCPA 1931); Ex parte Davis, 80 USPQ 448,450 (Bd. App. 1948) ("consisting of" defined as "closing the claim to the inclusion of materials other than those recited except for impurities ordinarily associated therewith.") A claim which depends from a claim which "consists of" the recited elements or steps cannot add an element or step. In the instant case the term "an orally acceptable vehicle" is broad because it is unclear what materials are the claims limited to by the transitional phrase "consisting of". Further the claimed limitation of abrasive to be from 0 to 5% wt. is not specific in light of the new limitation "consisting of" because the claimed value of RDA and IVSR are due to specific amount and combination of calcium sequestering agent and specific abrasive, it is not clear if the claimed properties of the dentifrice composition is with or without abrasive and/or which abrasive does applicant intends to limit the composition to. Additionally, regarding claim 22, the additional limitation of "further comprising abrasive silica" makes the claim indefinite because the phrase consisting of does not permit any further components in claim. It is not clear if applicant intends to claim only specific calcium sequestering agent and any combination of abrasive or specific calcium sequestering agent and specific abrasive in specific amount that provides the claimed property. Appropriate correction is requested.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35

U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 21-22 are rejected under 35 U.S.C. 102(b) as being anticipated by (EP A 0002184, translation of record).

EP teaches use of sodium polyphosphate (reads on calcium sequestering agent) in fine granulate for tooth cleaning either by itself or in combination with commercial tooth paste formulation referring to abrasive effect of sodium polyphosphate and intensify action of tooth cleaning without damaging the substance of teeth. The reference teaches calcium sequestering agent from 2 to 5% on page 1 of translation and the whole translation. The reference does not teach silica abrasive. Property of the dentifrice composition will be inherent to the composition since all required components are disclosed by prior art. Regarding the claimed property, patent office is not equipped with laboratory to test the property of the composition, since the claimed components are present in prior art, it is the position of the Examiner that the claimed property will be associated with the composition.

Response to Arguments

Applicant's arguments filed 04/14/11 have been fully considered but they are not persuasive.

Applicant argues that since EPA 0002184 does not teach each and every element of the claimed invention it cannot be said to anticipate the claims.

Applicant's arguments are not persuasive. As stated in the rejection above, the claimed polyphosphate has been disclosed in the claimed amount for tooth cleaning paste formulation. Burden is on applicant to provide evidence that the claimed properties would not be possessed by the prior art's tooth paste composition which has polyphosphate in claimed amount. Besides as stated in the 112.2 rejection above, it is not clear whether the abrasive is included in the composition or not. The language consisting of does not permit additional ingredients in composition.

6. Claims 21-22 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 01237700 (application no.), presented in IDS.

JP teaches dentifrice composition comprising 0.1% to 5.0% of calcium chelating/sequestering compound such as **sodium tripolyphosphates**, see abstract. The claimed property of RDA and IVSR will be inherent to the composition since the composition comprises the claimed chelating agent in the claimed range. Regarding the claimed property, patent office is not equipped with laboratory to test the property of the composition, since the claimed components are present in prior art, it is the position of

the Examiner that the claimed property will be associated with the composition. As stated in the 112.2 rejection above, it is not clear whether the abrasive is included in the composition or not. The language consisting of does not permit additional ingredients in composition.

Response to Arguments

Applicant's arguments filed 04/14/11 have been fully considered but they are not persuasive.

Applicant argues that since JP does not teach each and every element of the claimed invention it cannot be said to anticipate the claims.

Applicant's arguments are not persuasive. As stated in the rejection above, the claimed polyphosphate has been disclosed in the claimed amount for tooth cleaning paste formulation. Burden is on applicant to provide evidence that the claimed properties would not be possessed by the prior art's tooth paste composition which has polyphosphate in claimed amount. Besides as stated in the 112.2 rejection above, it is not clear whether the abrasive is included in the composition or not. The language consisting of does not permit additional ingredients in composition.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over EPA 0002184 in view of Kostinko et al. (US PG Pub 2003/0133882 A1).

EP teaches use of sodium polyphosphate (reads on chelating agent) in fine granulate for tooth cleaning either by itself or in combination with commercial tooth paste formulation referring to abrasive effect of sodium polyphosphate and intensify action of tooth cleaning without damaging the substance of teeth. The reference teaches calcium sequestering agent from 2 to 5% on page 1 of translation and the whole translation. The reference does not teach silica abrasive.

EP as discussed above does not explicitly teach pentasodium tripolyphosphate as calcium sequestering agent, chelating agent used in composition and abrasive silica.

Kostinko teaches abrasive composition for clear tooth paste, title. The reference teaches using **pentasodium tripolyphosphate** and sodium polymetaphosphate and tetra sodium pyrophosphate, see paragraph [0040]. Kostinko teaches abrasive composition for clear tooth paste, see title. The reference teaches using pentasodium tripolyphosphate and sodium polymetaphosphate and tetra sodium pyrophosphate, see paragraph [0040]. Abrasive silica is disclosed in examples, the dentifrice comprises abrasive silica in the range of 0.01% wt to 35 wt % and RDA of greater than about 50, a has value of less than about 50 and viscosity of greater than about 425,000cps, see page 1, paragraph [0010]. The dentifrice also includes premix with no silica in one of the

embodiments, see paragraph [0010]. The dentifrice composition has thickening agents, binders; humectants sweeteners etc. see paragraph [0034]. Paragraph [0035] discloses sorbitol, glycerin etc. Tables, III and IV and V show tetrasodium pyrophosphate in 0.5% amount.

It would have been obvious to one of ordinary skill to substitute pentasodium tripyrophosphate in the teachings of EP reference because substitution of one chelating agent with another would produce predictable results absent evidence of unexpected results. Besides as stated in the 112.2 rejection above, it is not clear whether the abrasive is included in the composition or not. The language consisting of does not permit additional ingredients in composition. From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments filed 04/14/11 have been fully considered but they are not persuasive.

Applicant argues the references individually and further argues that there is no teaching or suggestion in Kostinko of a dentifrice with an RDA value below 30. Kostinko teaches RDA values between 50 and 200, well above the claimed value of below 30.

Therefore, one of skill in the art would not have been motivated to combine the teaching in Kostinko with the teaching in the '184 application, let alone choose pentasodium tripolyphosphate as the chelating agent in a dentifrice with an RDA value below 30.

Applicant's arguments are not persuasive. Applicant argues that the claimed properties are not taught by Kostinko,. It is pointed out that since both the references are directed to dental cleaning compositions, utilization of one chelating agent over the other would have provided predictable results. Absent indication of unexpected results, it would be obvious to one of ordinary to utilize pentasodium tripolyphosphate as chelating agent over the other. Besides as stated in the 112.2 rejection above, it is not clear whether the abrasive is included in the composition or not. The language consisting of does not permit additional ingredients in composition. It is not clear if he claimed properties are due to abrasive or due to low amount of abrasive or additional abrasive.

9. Claims 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 01237700 (application no.), presented in IDS.

JP teaches the overlapping range of the chelating agent **sodium tripolyphosphates**, thus providing case of obviousness as the prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). JP teaches dentifrice composition comprising 0.1% to 5% of calcium chelating/sequestering compound such as sodium tripolyphosphates, see abstract. Thus overlapping range provides the reference to be

obvious to one of ordinary skill in the art at the time of instant invention. Regarding the claimed property, patent office is not equipped with laboratory to test the property of the composition, since the claimed components are present in prior art, it is the position of the Examiner that the claimed property will be associated with the composition. As stated in the 112.2 rejection above, it is not clear whether the abrasive is included in the composition or not. The language consisting of does not permit additional ingredients in composition.

Response to Arguments

Applicant's arguments filed 04/14/11 have been fully considered but they are not persuasive.

Applicant argues that since JP 01 237700 does not teach each and every element of the claimed invention it cannot be said to anticipate the claims (as defined above). Therefore, reconsideration and withdrawal of the rejection are respectfully requested.

Applicant argues that claimed RDA value will not be apparent to the composition, however this position is not persuasive to the examiner because the claimed components are disclosed by prior art, patent office is not equipped with laboratory to perform experiments, burden is on applicant to prove how the claimed properties of the prior art's components which are same as claimed with overlapping amounts as the claimed ones will provide different properties. It is held as discussed above that the overlapping amounts create case of obviousness, therefore one of ordinary would expect the claimed results by doing experimental manipulations of amounts of chelating

agent and abrasive. The reference does not teach abrasive so reads on claim 1 and thus would possess similar properties. As stated in the 112.2 rejection above, it is not clear whether the abrasive is included in the composition or not. The language consisting of does not permit additional ingredients in composition.

10. Claims 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP A 0002184.

EP teaches use of sodium polyphosphate in fine granulate for tooth cleaning either by itself or in combination with commercial tooth paste formulation referring to abrasive effect of sodium polyphosphate and intensify action of tooth cleaning without damaging the substance of teeth. The reference teaches calcium sequestering agent from 2 to 5% on page 1 of translation. The reference does not teach silica abrasive. Property of the dentifrice composition will be inherent to the composition since all required components are disclosed by prior art. Regarding claims 19-20, intended use of a dental composition does not hold patentable weight wherein the claims are drawn to a dentifrice composition. EP teaches the overlapping range of the chelating agent thus providing case of obviousness as the prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003).

Applicants arguments regarding claims 11-16 are moot since the claims have been cancelled and in light of new rejection due to consisting of language, the combined teachings of prior art make the claimed invention obvious. Besides as stated in the

112.2 rejection above, it is not clear whether the abrasive is included in the composition or not. The language consisting of does not permit additional ingredients in composition. It is not clear if he claimed properties are due to abrasive or due to low amount of abrasive or additional abrasive.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Snigdha Maewall/

Examiner, Art Unit 1612

/Gollamudi S. Kishore, PhD/

Primary Examiner, Art Unit 1612